REMARKS/ARGUMENTS

Claims 5, 6 and 11-22 are pending herein. The claims have been amended to further clarify the patentable differences between the present invention and the prior art. Specifically, independent claim 5 now recites a method for "treating" severe diabetic retinopathy rather than "ameliorating" the condition, and limitations drawn to the second embodiment of the treating compound have been cancelled from independent claim 5. Claim 6 has been amended to correct matters of form and to be consistent with respect to rewritten independent claim 5, and claims 7-10 have been cancelled. New claims 11-22 have been added hereby, as supported, for example, by the experimental data presented in the original specification on pages 8-11 thereof. Applicants respectfully submit that no new matter has been added.

Claims 5-10 were rejected under §102(b) over JP '547. To the extent that the PTO might attempt to assert this rejection against the new and rewritten claims submitted above, it is respectfully traversed.

The PTO admitted that JP '547 discloses the use of fidarestat to retard or inhibit diabetic retinopathy simplex, but asserted that the treatment anticipates the claimed invention. Applicants respectfully submit, however, that the PTO is incorrect.

As explained in the present specification beginning at the paragraph bridging pages 1 and 2, diabetic retinopathy starts from simple diabetic retinopathy (the affliction treated in the primary reference) and becomes serious during the development of the stages of preproliferative diabetic retinopathy and proliferative diabetic retinopathy. Diabetic retinopathy progresses in stages from simple diabetic

retinopathy to preproliferative diabetic retinopathy and further to proliferative diabetic retinopathy in this order. It is well known that the clinical conditions associated with the pathological stage of simple diabetic retinopathy are different from those in the pathological stages of preproliferative diabetic retinopathy or proliferative diabetic retinopathy. In the case of simple diabetic retinopathy, a microaneurysm is formed, and by mascular hyperpermeability, high exudate and retinal edema come to be recognized. In contrast, in preproliferative diabetic retinopathy, retinal vascular disturbance/occlusion causes soft exudate, IRMA (intra-retinal microvascular abnormalities) and macular tortuosity to occur due to ischemia of retinal tissues. In proliferative diabetic retinopathy, neovascularization are newly formed, and vitreous hemorrhage and tractional retinal detachment are recognized bringing about a serious disorder in visual acuity.

As such, Applicants respectfully submit that one skilled in the art would readily recognize and appreciate that the clinical conditions of severe diabetic retinopathy (preproliferative diabetic retinopathy and proliferative diabetic retinopathy), the conditions treated here, are not simply aggravated conditions of simple diabetic retinopathy disclosed in connection with JP '547, but are instead conditions whose characteristic properties are different from those of simple diabetic retinopathy.

JP '547 discloses that some drugs have been reported to be effective for such simple diabetic retinopathy. Moreover, the progress of simple retinopathy can be suppressed at some level by strict blood glucose control.

On the other hand, to date, no drug that is effective for severe diabetic retinopathy is known. Moreover, the progress of severe diabetic retinopathy cannot be suppressed by strict blood glucose control. It is said that panretinal photocoagulation or vitrectomy is considered to be effective as a method for treating severe diabetic retinopathy; see the discussion in the first paragraph on page 3 of the specification. Accordingly, Applicants respectfully submit that one skilled in the art would readily conclude that simple diabetic retinopathy is considered to be a different disease from severe diabetic retinopathy with respect to the methods of treatment therefor.

In the present invention, a spontaneous diabetic Torii (SDT) rat is used as a model showing pathological conditions similar to those of human severe retinopathy. An SDT rat shows symptoms of IRMA and tractional retinal detachment, which are symptoms of severe diabetic retinopathy; see the discussion in the paragraph bridging pages 4 and 5 of the specification. On the other hand, in JP '547, an STZ-administered rat was used as a model showing pathological conditions similar to those of human simple diabetic retinopathy. An STZ-administered rat is used only for estimating simple diabetic retinopathy and cannot be used for estimating severe diabetic retinopathy, because an STZ-administered rat does not show severe diabetic retinopathy symptoms.

Prior to the present invention, model animals for severe diabetic retinopathy have not been reported, so the effectiveness of SNK-860 on severe diabetic retinopathy could not be verified. Accordingly, Applicants respectfully submit that there is no disclosure or suggestion in the prior art as to whether SNK-860 would or

could possibly have an effect upon severe diabetic retinopathy. Applicants respectfully submit that there is certainly no disclosure or suggestion that SNK-860 could have such an effect based on the disclosure in JP '547. Indeed, Applicants respectfully submit that the Applicants first discovered and evaluated the effectiveness of SNK-860 on severe diabetic retinopathy using a SDT rat as a model showing pathological conditions similar to those in human severe diabetic retinopathy.

Moreover, Applicants respectfully submit that any skilled artisan would appreciate that the useful effects of a drug used to treat simple diabetic retinopathy cannot be predicted to extend to another condition, such as treating severe diabetic retinopathy, and one skilled in the art would not have had any logical basis or reasonable expectation that a similar effect would necessarily be achieved. As explained previously, simple diabetic retinopathy is different from severe diabetic retinopathy with respect to the clinical conditions and methods of treatment. As a basic assumption in this technical field, it is well established that predictions as to the potential effects of a drug on one clinical condition cannot be effectively made based on its effects with respect to another clinical condition.

For at least the reasons explained above, Applicants respectfully submit that the prior art of record fails to disclose or suggest each and every feature recited in independent claim 5. As such, Applicants respectfully submit that independent claim 5, and all claims depending directly or indirectly therefrom, define patentable subject matter over the prior art of record. Accordingly, Applicants respectfully request that the above rejection be reconsidered and withdrawn.

If the Examiner believes that contact with Applicants' attorney would be advantageous toward the disposition of this case, the Examiner is herein requested to call Applicants' attorney at the phone number noted below.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-1446.

Respectfully submitted,

May 21, 2009
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